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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-22-22IX; Docket No. CDC-2022-0113]

Proposed Data Collections Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden, invites the general public and other federal agencies to take this opportunity to comment on proposed information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Study of PrEPline reported PrEP-adherent patients with HIV acquisition. The purpose of this project is to understand preferences for long-acting pre-exposure prophylaxis (LA-PrEP) products for HIV prevention among potential users and providers.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2022-0113 by either of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.

- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7118; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection

before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Study of PrEPline Reported PrEP-Adherent Patients with HIV Acquisition - New - National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

As the use of antiretroviral preexposure prophylaxis (PrEP) continues to grow in the United States, despite the high effectiveness of PrEP (>95%) when taken as prescribed, sporadic case reports are appearing that document HIV acquisition among patients apparently adherent to the prescribed PrEP dosing schedule. Because PrEP medications can alter the immune responses on which HIV testing relies, ambiguous test results also occur and present diagnostic challenges to clinicians. Careful selection of tests, and the timing and sequence in which they are done to confirm whether HIV infection has occurred, and resistance characteristics of the virus, if present, are increasingly necessary. In addition, objective measures of the amount of PrEP drug in patients around the time of potential HIV acquisition is important to assess medication adherence and further characterize PrEP effectiveness in "real world" settings. A system of active case detection and confirmation of HIV acquisition in PrEP-adherent patients was successfully piloted and can now be continuously implemented by leveraging clinician contacts to the National Clinician Consultation Center's (NCCC) PrEPline, PEPline, and HIV Warmline; and by obtaining consent for specimens to be shipped to the University of California San Francisco (UCSF) or the Centers for Disease Control and Prevention (CDC) for research assays. Monitoring and improving our understanding of the occurrence of ambiguous test results, HIV acquisition among PrEP patients, and their relationship to medication adherence is necessary to inform

clinician management of these patients and to ensure clear messaging about PrEP "failures" (most of which are a result of non-adherence) and HIV testing in PrEP patients.

The PrEPline (and other "warmlines" operated by NCCC) and health department HIV case reporting are complementary sources of case identification. Clinicians call the PrEPline with testing and management questions soon after receiving test results for patients continuing or re-initiating PrEP, or transitioning from PEP to PrEP, and have direct access to clinical records and patients. In addition, clinicians call the HIV Warmline with questions about HIV screening/testing results and best practices in evaluation and management of patients who acquire HIV while on PrEP. Health departments typically identify such patients later (especially if by periodic review of National HIV Surveillance System data) and then must reach out to clinicians for clinical records, and sometimes for patient consents for research specimens, to confirm HIV status.

The goals are to conduct a study that obtains consent and case report information from clinicians calling the NCCC's PrEPline and HIV Warmline to help identify, assess, and discuss clinical management of: 1) PrEP patients with ambiguous HIV test results; and 2) patients who acquire HIV infection while being prescribed PrEP. This information will allow CDC to: a) assess the proportion of clinicians with eligible patients who provide case information from medical records; b) measure the completeness and utility of data collection forms to be sent to

CDC; c) assess the proportion of clinicians with eligible patients who refer patients to participate in a UCSF National Institutes of Health-funded study called SeroPrEP that involves specimen testing to be performed at designated specialty reference/research labs; and d) assess the proportion of eligible patients who consent to enroll in the SeroPrEP study and provide specimens to reference/research labs to confirm HIV status and measure PrEP drug levels.

The study's target population includes clinicians calling to NCCC within 90 days of a reactive/detectable HIV test (in cases of oral PrEP use) or 180 days of a reactive/detectable HIV test (in cases of long-acting injectable cabotegravir use) about case-patients who reported:

- Regularly taking prescribed oral PrEP medication (emtricitabine or lamivudine co-formulated with either tenofovir disoproxil fumarate or tenofovir alafenamide, or oral cabotegravir) either:
  - Throughout the interval from the last negative HIV test to the date of first reactive or detectable HIV test results; *or*
  - During the interval from the last negative HIV test to stopping, within two months before the date of first reactive or detectable HIV test results (without an intervening HIV test).
- Regularly receiving injections with long-acting cabotegravir either:

- Throughout the interval from the last negative HIV test to the date of first reactive or detectable HIV test results; *or*
- During the interval from the last negative HIV test to stopping injections, within 18 months before the date of first reactive or detectable HIV test results.

and for whom either:

- Laboratory tests confirm acquisition of HIV infection while reportedly medication-adherent; *or*
- Laboratory tests are ambiguous (do not clearly confirm HIV status).

The study data will be collected via phone interviews with clinicians calling the NCCC PrEPline (or other warmlines) for clinical advice about diagnostic testing and clinical management of patients with ambiguous HIV test results or diagnosed HIV infection while taking PrEP medications. Data collection will last approximately five years.

Participation is voluntary. An estimated one-time reporting burden for this collection will be approximately 62 hours. This includes the time burden associated with the Provider Verbal Consent and completing the Patient Data Collection Form. CDC will enroll approximately 125 providers, at 10 minutes per Provider Verbal Consent and 20 minutes per Patient Data Collection Form, to provide patient information over five years.

There are no costs to respondents other than time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden (in Hours)
Clinician	Provider Consent Form	125	1	10/60	21
Clinician report of patient information	Patient Data Collection Form	125	1	20/60	42
Total					63

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

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